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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,182	BANKS, WILLIAM A.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *6-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

2. Applicant's remarks and amendments filed 5 July 2005 have been entered. Claims 1 – 5 are pending and under examination; claims 6 – 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1 March 2005.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

4. The following rejections from the previous office action are withdrawn:

The rejections under 35 USC 102. Applicant's amendment, requiring co-administration of leptin, obviate the rejections as neither Mostyn nor Gamaro teach administration of leptin.

The rejection under 35 USC 103. Applicant's amendment, requiring that the administration of the agent be effective to modulate the transport of leptin across the BBB, is sufficient to obviate the rejection as Gamaro neither teaches nor suggests modulation of transport.

Rejections Maintained and Necessitated by Amendment

Claim Objections

5. Claims 3 – 5 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 – 5 are drawn to leptins, variants, analogs, fusion proteins, chemically modified derivatives of leptin and fragments thereof, which is a broader group of compounds than leptin, as recited in claim 1.

Claim Rejections - 35 USC § 112

6. Claims 1 – 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increased transport of leptin across the blood-brain barrier (BBB) following coadministration of leptin and intravenous or intraperitoneal epinephrine, cirazoline, benoxathian, phentolamine, yohimbine, prasozin, adenosine, or glutamate, does not reasonably provide enablement for increased transport of leptin across the BBB following administration by any other route of administration, or with any other compound, nor for co-administration of leptin variants, analogs, fusion proteins, derivates or fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

On p. 11 of the remarks applicant argues that not every member of a class need to be enabled in order to provide support for enablement of a genus claim, and cites *Atlas Powder Co. v. El du Pont de Nemours & Co.* as providing support for this argument. The *Atlas* court ruled that:

> "Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude * * * possible inoperative substances * * * *" In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971)."

The examiner acknowledges that applicant has taught how to coadminister leptin with a broad range of compounds. The claims are drawn to methods of modulating the transport of leptin across the BBB and thus the consideration of whether the claims are enabled depends on whether the recited methods are sufficient to accomplish the goal recited in the preamble. In the instant case, there are so many non-enabled embodiments disclosed in the specification that the claims cannot be considered enabled over their full scope.

The specification discloses that intraperitoneal administration of epinephrine increases brain uptake of intravenously-injected radiolabelled leptin. Furthermore, the specification discloses the administration of tyrosine and phenylalanine in a similar method (p. 22 – 23) but indicates that while tyrosine is marginally effective phenylalanine is not effective. Similarly p. 24 indicates that argenine, phenylalanine, tryptophan, leucine, threonine, and leucine have no effect on transport of leptin across the BBB. A skilled artisan would most likely conclude that

amino acids in general are not effective in increasing the amount of leptin that crosses the BBB, as six of them clearly do not work. The data presented on p. 25 indicate that while epinephrine is a neurotransmitter and is effective in modulating transport of leptin across the BBB when administered intravenously, neither epinephrine nor any other neurotransmitter administered by applicant is effective when administered intracerebralventricularly (ICV). Furthermore no other neurotransmitter is effective when administered IV.

Furthermore, the specification indicates that adrenergic agonists in general are not effective in modulating the transport of leptin across the BBB. While ispoproterenol and arterenol are effective in this method, neither clonidine nor L-phenylephrine are effective (specification, p. 26). Adrenergic antagonists as a generic class are also not effective in modulating leptin transport across the BBB: phentolamine, yohimbine, and prasozin decrease leptin uptake, but D,L-propanolol does not modulate uptake. Additionally, while the alpha-1 adrenergic agonist cirazoline and the antagonist benoxathian modulate uptake, others listed in table 9 (p. 28) do not. The specification indicates that TNF-alpha does not modulate leptin uptake (p. 29). While TNF-alpha knockout mice show altered responses to leptin saturation (p. 29), this does not indicate that cytokines in general are effective modulators, or that TNF-alpha is even involved in leptin transport. In fact TNF-alpha induces production of the leptin protein (see Finck et al., American Journal of Phsyiology 278:R537-R543), so the data presented by applicant are not supportive of the conclusion that cytokines increase leptin transport across the BBB.

On p. 12 of the remarks, applicant argues that at least one member of each class is enabled, and that "typically, the specification provides more examples of compounds that do modulate transport than those that do not". The examiner acknowledges that at least one member of each class is enabled, although in some instances as single embodiment falls into more than one class (e.g. epinephrine is an adrenergic agonist and a neurotransmitter). The claims are akin to a single means claim and are properly rejected for having undue breadth under 35 USC 112, first paragraph. In certain instances, for example neurotransmitters and amino acids, applicant has not enabled the structural or functional class in general, but has provided a single example falling within the scope of the class. Thus claim 1 is akin to a single means claim; see MPEP § 2164.08(a) for a discussion of single means claims. In other instances, for example amino acids, the specification discloses more non-working examples than working examples and therefore the claims clearly are not enabled over their full scope.

Applicant also cites *In re Wands* as providing support for the argument that an extensive amount of experimentation is not necessarily undue. The examiner agrees. However, there are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988). In the instant case, given the complex nature of the invention, the breadth of the claims, the few working examples, and the disclosure of many non-working embodiments that clearly fall within the scope of the claims, the examiner believes that the Wands and Atlas decisions, taken as a whole, support the rejection of claims 1 – 5 under 35 USC 112, first paragraph for not being enabled over their full scope.

Applicant also cites *In re Fischer* as providing support for the enablement of the full scope of the claims. Applicant argues that the Fischer court ruled that "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim then the enablement requirement is satisfied." (remarks, p. 12). The examiner believes that applicant's interpretation of the *Fischer* decision is incorrect. The relevant text from Fischer appears below:

> It is equally apparent, however, that he [the inventor] must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. (emphasis added)

Clearly the scopes of applicant's claims are much broader than what is enabled by the specification. Furthermore, applicant's reliance on enablement of a single member of a class of products by showing how to make and use the products is not relevant, as the instant claims are drawn to methods. In order for a method claim to be considered enabled, the steps must achieve the goal stated in the preamble. In the instant case, many of the embodiments that fall within the scope of the claims will not work.

On p. 13 of the remarks applicant argues that the specification discloses many routes of administration commonly used in the art. The examiner concedes that administration of agents by various routes are well within the skill of the artisan. However the specification discloses that several of these routes of administration do not work for the claimed methods. For example, Example 6 (p. 24 – 25) of the specification discloses that of five neurotransmitters administered (acetylcholine, dopamine, epinephrine, histamine, and serotonin), none of them are effective in modulating transport of leptin across the BBB, when these agents are administered ICV. Furthermore, the specification discloses (p. 25, lines 15 – 18) that of all neurotransmitters administered IV, only epinephrine is effective in modulating the transport of leptin across the BBB. As explained on p. 5 of the previous office action, an intracisternal injection is the same as an ICV injection and therefore administration of neurotransmitters by the intracisternal route also will not work. In fact, there are no working examples of any compounds modulating leptin transport after ICV administration. Because the artisan would have to resort to extensive experimentation in order to find agents which modulate transport after ICV injection, and because the specification provides no guidance to the artisan in how to select such an agent and all the examples of ICV administration fail to modulate leptin transport, it would require undue experimentation on the part of a skilled artisan to practice the claimed methods across their full scope.

Applicant also argues that leptin and variants thereof, as recited in claims 3 – 4 and encompassed by dependent claim 5, are well known in the art. The examiner concedes that leptin is well-known, but the variants as claimed are not limited by structure. The only requirement is that the leptin be "biologically active" and retain the ability to cross the BBB. Applicant has not explicitly defined "biological activity" and the term is so broad that it includes, for example, fragments as small as six consecutive amino acids which retain the activity of being able to produce antibodies (see Hopp et al., 1981. PNAS 78:3824-3828). Furthermore the term analogs is so broad that it appears to include any structure. Claims 3 – 5 are very broad in that they are drawn to a genus that is essentially infinite because it allows for an unlimited number of substitutions, deletions, and fragments. The claimed leptin variants, fragments, and analogs are not limited by structure and there is not sufficient guidance in the specification to allow a skilled artisan to make and use the claimed leptin variants, analogs, and fragments. Furthermore the specification does not disclose results of any experiments other than those in which leptin was administered, and the teachings of Peelman cited in the previous

office action indicate that this molecule is very sensitive to even single amino acid changes. Thus the art is unpredictable.

Applicant also cites *In re Borokowski* as providing support for the argument that experimentation is not undue. In *Borokowski*, the court ruled that having to conduct a few hours' worth of experimentation is not undue for a skilled artisan to optimize a process. The fact pattern of the instant case is significantly different from *Borokowski*. In the instant case, the specification discloses working examples, but the claims are so broad that they cover a large number of embodiments which the specification discloses are inoperative. There is little guidance as to how to enable these embodiments. For example there is no guidance as to how to modulate BBB transport of leptin by administering an agent ICV, and all the examples disclosed in the specification indicate that it is not effective. Furthermore there is only one example of a neurotransmitter that works in the claimed method. It would clearly take a skilled artisan much more than a few hours' worth of experimentation to practice the invention over the full scope of the claims, and thus the citation of *Borokowski* is not germane.

7. Claims 1 – 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to broad classes of agents which are not structurally limited. For example, claim 1 is drawn to neurotransmitters, which can be small molecules such as dopamine, single amino acids such as glutamate, or proteins such as neuropeptide Y. Similarly, the terms "agonists" and "antagonists" are functional, not structural definitions. As stated in the previous office action, certain embodiments that fall within the scope of leptin variants are described in the specification, although others such as "fragments" of leptin and "metabolites" of all agents do not meet the written description requirement. Claims 3 – 5 are very broad in that they are drawn to fragments of leptin, fragments of the analogs, fragments of the derivatives, and fragments of fusion proteins. The claims do not recite which parts of the sequence can be varied, which can be deleted, where insertions can be made, or even which parts of the sequence must be present for the molecule to be considered "leptin". The instant disclosure of

a handful of molecules, however, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there are not sufficient structure/function correlations presented in the specification to allow the skilled artisan to conclude that applicant possessed the invention as claimed. There is not identification of which regions of a the molecules recited in claim 1, part ii) are required, nor is there an identification of which regions of leptin or the fragments, variants, or modifications thereof are required. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genera of molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicant cites MPEP 2163 and the decision from *Hybridtech* as support for the argument that what is well-known need not be described in the specification. While this is of course the case, the instantly-claimed variants, analogs, modified leptins, and fragments of all the above do not meet the description requirement. The examiner acknowledges that the specification teaches 83% identity as a preferred leptin, but the claims still include non-described analogs, fragments, modifications, and variants. The percentage identity requirement does not appear in the claims.

Applicant cites U.S. Patent 6,734,160, 6,429,290, 6,471,956, 6,350730, and 6,309,853 as providing support for the argument that the agents recited in the claims are fully described. The examiner disagrees. 6,734,160 does disclose fragments but there is no disclosure of which fragments retain the ability to be transported across the BBB, as required by claims 3 – 5. Neither the art nor the specification indicates a correlation between the claimed structure (i.e. a leptin fragment) and the function (transport), and thus the description requirement has not been met. 6,471,956 and 6,429,290 disclose modified leptins but similarly fail to disclose which regions are required for the claimed function, the ability to be transported across the BBB. Similarly 6,350,730 and 6,309,853 disclose fragments and analogs but do not disclose which regions are required for transport.. Thus neither the art nor the specification describes the claimed invention, and therefore the situation is considerably different from the *Hybridtech* case. Thus the rejections under 35 USC 112, first paragraph for failing to provide adequate written description are maintained.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 – 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, from which all other claims depend, recites "an effective amount of exogenous leptin" in part (i). This term is indefinite because there is no recitation of what the amount is to be effective for. The conclusion of claim 1 requires that the amount of the agent administered in part (ii) be effective to modulate the transport of leptin across the BBB, but this refers only to part (ii) and not to part (i). A skilled artisan would not be able to determine the metes and bounds of the claims, because the artisan would not know what constitutes an effective amount of leptin and would not know how to determine what constitutes an effective amount in the absence of knowing what it is to be effective for.

Claim Rejections - 35 USC § 103

10. Claims 1 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banks et al. (1996. Peptides 17:305-311, cited on IDS) in view of Borges et al. (1994. Changes in brain microvessel endothelial cell monolayer permeability adrenergic drugs. European Journal of

Pharmacology 269:243-248) and Caro et al. (The Lancet 348:159-161, cited in previous office action).

Banks et al. teach a method of administering leptin to a mammal. Banks teaches that leptin suppresses food intake (second paragraph on p. 305) and teaches intravenous administration of exogenous leptin sufficient to cross the BBB (see Figure 1 on p. 305 as well as p. 310, Results). The amount used by Banks was effective to cross the BBB. Banks does not teach or suggest administration of epinephrine for increased transport of leptin.

Borges teaches administration of epinephrine *in vitro* modulates permeability of bovine brain microvessel endothelial cells. Borges teaches administration of several adrenergic agonists and antagonists, including adrenaline (which is a synonym for epinephrine) at varying concentration and teaches which concentrations are effective in modulating transport of impermeable molecules across the BBB. Borges measured transport by determining the amount of labeled agent that crosses the BBB; this is similar to the method used by applicant wherein the amount of radiolabeled leptin that crosses the BBB was determined and also similar to the method of Banks. Borges teaches that bovine brain microvessel endothelial cells are a suitable model for the blood brain barrier (see p. 244, first paragraph). Borges does not teach or suggest administration of leptin.

Caro teaches a positive correlation between serum leptin levels and body mass index (BMI), a measure of obesity (see Figure 1, top panel). Caro also teaches a negative correlation between the ratio of cerebrospinal leptin : serum leptin and BMI (Firgure 1, bottom panel). Caro teaches that leptin must cross the BBB to be active at its target receptors in the hypothalamus (p. 160, bottom of second column), and hypothesizes that brain transport of leptin is the rate limiting step in leptin action (p. 161, first paragraph). Caro also teaches that administration of additional leptin would be in effective in reducing weight or signaling satiety because the transporters are saturated.

It would have been obvious to one of ordinary skill in the art to administer exogenous leptin and epinephrine in an amount effective to modulate transport of leptin across the BBB, with a reasonable expectation of success. The motivation to do so is to increase the amount of leptin that reaches the hypothalamus, thereby signaling satiety to obese patients. This motivation is provided by Caro. It would be reasonable to expect success, as Borges teaches that administration of epinephrine is sufficient to modulate transport of impermeable molecules,

and Banks teaches that leptin is an impermeable molecule because the transport system is saturable.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
August 11, 2005

SHARON TURNER, PH.D.
PRIMARY EXAMINER
8-15-05